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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,522	09/26/2001	Preeti Lal	PF-0221-2 DIV	2875

7590 02/22/2002

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EXAMINER	
STEADMAN, DAVID J	
ART UNIT	PAPER NUMBER
1652	6

DATE MAILED: 02/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/965,522	Applicant(s) LAL ET AL.	
	Examiner David J. Steadman	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,12,30-45 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,11,12,30-45 and 56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

Claims 1, 11, 12, 30-45, and 56 are pending in the application.

Applicants' cancellation of claims 2-10, 13-29, 46-55, and 57 in Paper No. 4, filed 09/26/01 is acknowledged.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1 and 56, drawn to the polypeptide of SEQ ID NO:1, classified in class 530, subclass 350.

II. Claim(s) 11, 31, 32, 34, 37, 38, and 40-43, drawn to polyclonal and monoclonal antibodies that bind the polypeptide of SEQ ID NO:1 and compositions thereof, classified in class 530, subclass 388.1 and 389.1.

III. Claim(s) 12, drawn to the polynucleotide of SEQ ID NO:2, classified in class 536, subclass 23.5.

IV. Claim(s) 30, 33, 35, and 44, drawn to a diagnostic test for a condition or disease or a method of detecting a polypeptide using an antibody that binds the polypeptide of SEQ ID NO:1, classified in class 435, subclass 7.1.

V. Claim(s) 36 and 39, drawn to methods of producing polyclonal and monoclonal antibodies that bind the polypeptide of SEQ ID NO:1, classified in class 530, subclass 388.1 and 389.1.

VI. Claim(s) 45, drawn to a method of purifying a polypeptide using an antibody that binds the polypeptide of SEQ ID NO:1, classified in class 530, subclass 413.

2. The inventions are distinct, each from the other because:

3. The polynucleotide of Group III, the polypeptide of Group I, and the antibody of Group II each comprises a chemically unrelated structure capable of separate manufacture, use, and effect. The

polynucleotide of Group III has other utility besides encoding polypeptides such as a hybridization probe, the polypeptide of Group I can be made by another method such as purification from the natural source or *in vitro* synthesis, and the antibody of Group II can be used for the purification of the polypeptide of Group I.

4. The polynucleotide of Group III is unrelated to the method(s) of Group IV-VI as it is neither used nor made by the method(s) of Groups IV-VI.

5. The polypeptide of Group I and the methods of Groups IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used to treat disorders associated with decreased phosphate levels as disclosed at page 22 of the specification.

6. The antibody of Group II and the methods of Groups IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group II can be used to inhibit the activity of the polypeptide of SEQ ID NO:1.

7. The methods of Groups IV-VI are independent as they comprise different steps, utilize different products and yield different results.

8. Because these inventions are distinct for the reasons given above, have separate classifications, and/or each of the inventions listed as Groups I-VI requires a separate search, restriction for examination purposes as indicated is proper. "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02" (see

MPEP 803). The inventions listed as Groups I-VI require divergent patent and non-patent literature and/or sequence searches, thus requiring a serious burden on the examiner.

Conclusion

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 2:00 pm and from 3:30 pm to 5:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600